510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k121012

B. Purpose for Submission:

The submission is to obtain clearance for FlexLab 3.6 as an accessory to clinical laboratory analyzers such as ARCHITECT c8000 analyzer. The manufacturer uses the ARCHITECT c8000 to demonstrate FlexLab 3.6 barcode sample ID transmission to the analyzer and analytical equivalence to manual sample introduction versus automated sample introduction on the analyzer.

C. Manufacturer and Instrument Name:

Inpeco, FlexLab 3.6 (distributed as: Abbott Laboratories ACCELERATOR a3600)

D. Type of Test or Tests Performed:

Quantitative, ion selective electrode (ISE)

E. System Descriptions:

1. Device Description:

The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.

The system consolidates multiple Analytical instruments into a unified workstation that communicates with Hospital information System (HIS).

The automation software provides for workload management, sample routing to relevant analytical instrument based on sample orders coming from LIS (Laboratory Information System) and instrument operational status monitoring. This is accomplished through communication connections between the automation, analytical instruments and LIS or middleware.

Pre-analytical and post-analytical processing are as follows: sample loading and unloading and sample identification by barcode read (previously done by the analyzer), sample transport along the system and routing to relevant modules, loading and unloading in centrifuge, de-capping, sealing, de-sealing, storing in a

temperature controlled environment, aliquoting, aliquot sample capping, and sample presentation to connected analytical instruments.

2. Principles of Operation:

   Ion selective electrode (ISE) using potentiometry

3. Modes of Operation:

   The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.

   The system consolidates multiple Analytical instruments into a unified workstation. The automation software provides for workload management, sample routing to relevant analytical instrument based on sample orders coming from LIS (Laboratory Information System) and instrument operational status monitoring. This is accomplished through communication connections between the automation, analytical instruments and LIS or middleware.

4. Specimen Identification:

   Bar coded sample tubes read directly by analyzer when placed on LSH, or sample bar code read by FlexLab 3.6 and electronically transferred to the ARCHITECT c8000 analyzer when presented at the aspiration point

5. Specimen Sampling and Handling:

   The analyzer interface module provides the path required to move sample tubes to the analyzer and directly loaded into the ARCHITECT via the LSH or via FlexLab 3.6 Sampling takes place directly from the primary tube presented to the aspiration point by the FlexLab 3.6 track or spur.

6. Calibration:

   – Provided in k093318

7. Quality Control:

   – Provided in k093318

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes____X____ or No_____

F. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJE – Analyzer, chemistry (photometric, discrete), for clinical use	Class I	21 CFR § 862.2160	Clinical Chemistry (75)
JQP – Calculator/data processing module, for clinical use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)
CEM – Potassium test system	Class II	21 CFR § 862.1600	Clinical Chemistry (75)
CGZ – Chloride test system	Class II	21 CFR § 862.1170	Clinical Chemistry (75)
JGS – Sodium test system	Class II	21 CFR § 862.1665	Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

   The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.

   The system consolidates analytical instruments, such as the ARCHITECT c8000System into a unified workstation that performs a variety of instrument specific assays such as Sodium, Potassium and Chloride.

   Sodium, Potassium and Chloride measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance.

2. Special Conditions for Use Statement(s):

   Prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

APS Accelerator - k093318 (CEM)

2. Comparison with Predicate Device:

Item	Device	Predicate: ARCHITECT c8000 with embedded ICT Module integrated to ACCELERATOR APS
Intended Use	The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory. The system consolidates analytical instruments, such as the ARCHITECT c8000System into a unified workstation that performs a variety of instrument specific assays such as Sodium, Potassium and Chloride.	Same
Principle of Operation	ARCHITECT c8000 Systems utilize photometric and potentiometric technology for analyte detection	Same
Sample Containers	Primary and secondary tubes	Same
Sample Handling	Directly loaded into the ARCHITECT via the LSH or via FlexLab 3.6	Same
Sample Pre-Analytics (centrifuge, de-cap, re-seal, aliquoter)	Sample tubes are centrifuged, de-capped, re-sealed, and aliquoted manually by laboratory personnel or automatically by FlexLab 3.6	Same
Sample Pre-Analytics (re-cap)	Sample tubes are re-capped manually by laboratory personnel	Same

Item	Device	Predicate: ARCHITECT c8000 with embedded ICT Module integrated to ACCELERATOR APS
Sample Transportation	External to analyzer: by FlexLab 3.6 transport carriers identified on the system by RFID tags Internal to analyzer: N/A, sample presented to analyzer via FlexLab 3.6 for aspiration.	External to analyzer: Same Internal to analyzer: Same
Sample Identification from bar coded tubes	Bar coded sample tubes read directly by analyzer when placed on LSH, or sample bar code read by FlexLab 3.6 and electronically transferred to the ARCHITECT c8000 analyzer when presented at the aspiration point	Same
Sample Storage/Retrieval	Manually stored and retrieved by laboratory personnel or automatically stored/retrieved by FlexLab 3.6	Same
Test Orders	Unidirectional from Laboratory Information System (LIS) or middle ware to analyzer	Same
Test Results	Unidirectional from Laboratory Information System (LIS) or middle ware to analyzer	Same
LAS Communication	ARCHITECT software communicates with FlexLab 3.6 via LAS interface	Same
LIS Communication	ARCHITECT software communicates with hospital LIS via FlexLab 3.6 data management system interface	Same

I. Special Control/Guidance Document Referenced (if applicable):

Safety requirements for electrical equipment for measurement, control, and laboratory use. UL61010-1:2001 (2nd edition)

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

– Provided in k093318

b. Precision/Reproducibility:

– Provided in k093318

c. Linearity:

– Provided in k093318

d. Carryover:

- Not applicable

e. Interfering Substances:

- Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Comparison studies:

a. Method comparison with predicate device:

The method correlation comparison study was conducted between an ARCHITECT c8000 analyzer with FlexLab 3.6 and an ARCHITECT c8000 analyzer with ACCERLERATOR APS yielded the following results for the Sodium, Potassium and Chloride assays.

Chloride:

Regression Method	Number of Specimens	Correlation Coefficient	Slope (95% CI)	Y-axis Intercept (95% CI)	Mean % Bias
Least Squares	100	0.9993	1.00 (0.99, 1.01)	- 0.90 (-1.70, - 0.09)	-0.8
Deming	100	0.9993	1.00 (0.99, 1.01)	- 0.97 (-1.65, -0.29)	
Passing-Bablok	100	0.9993	1.00 (0.99, 1.01)	- 0.89 (-1.61, -0.23)	

Potassium:

Regression Method	Number of Specimens	Correlation Coefficient	Slope (95% CI)	Y-axis Intercept (95% CI)	Mean % Bias
Least Squares	100	0.9995	1.00 (1.00, 1.01)	-0.06 (-0.09, -0.03)	-0.8
Deming	100	0.9995	1.00 (1.00, 1.01)	-0.06 (-0.09, -0.03)	
Passing-Bablok	100	0.9995	1.00 (1.00, 1.01)	-0.05 (-0.07, -0.02)	

Sodium:

Regression Method	Number of Specimens	Correlation Coefficient	Slope (95% CI)	Y-axis Intercept (95% CI)	Mean % Bias
Least Squares	100	0.9993	1.01 (1.00, 1.02)	-2.37 (-3.50, -1.25)	-0.6
Deming	100	0.9993	1.01 (1.00, 1.02)	-2.48 (-3.63, -1.33)	
Passing-Bablok	100	0.9993	1.02 (1.01, 1.03)	3.08 (-4.72, -1.97)	

b. Software/Hardware Verification and Validation:

Various functional test protocols were used to validate the barcode read and transmission capabilities for the FlexLab 3.6/Architect c8000 system. The test protocols were found to be acceptable.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.